

REMARKS/ARGUMENTS

Applicants have received and carefully reviewed the Office Action mailed March 15, 2010. Claims 1, 27, 29-33, 40-49, 61, and 62 are currently pending, with claims 29-33 previously withdrawn from consideration. Claims 1, 27, 40-49, 61, and 62 have been rejected. Applicants respectfully traverse all adverse assertions and rejections presented in the Office Action. With this amendment, claims 1 and 40 have been amended to clarify the relationship among certain claim elements. No new material has been added, and the amendments are supported, by at least the drawings, along with the originally filed specification and claims. Favorable consideration of the above amendments and the following remarks is respectfully requested.

Claim Rejections – 35 USC § 112

Claims 40-49 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Office Action asserts that the originally filed specification does not support the claimed limitation of “a connector disposed between the flexible disk and the hemostatic body to couple the flexible disk to the hemostatic body”. Applicants respectfully traverse this rejection, and direct the Examiner’s attention to the specification from the second paragraph of page 21 through the second paragraph of page 22, as well as Figure 11, for discussion related to neck 404 connecting disk 402 and body 406. One of ordinary skill in the art will have no difficulty recognizing neck 404 as an illustrative example of the claimed connector. Withdrawal of the rejection is respectfully requested.

Claim Rejections – 35 USC § 103

Claims 1, 40-46, and 61 were rejected under 35 U.S.C. §103(a) as being unpatentable over Nash et al. (U.S. Patent No. 5,700,277) in view of Hannam et al. (U.S. Patent No. 5,649,959). After careful review, Applicants must respectfully traverse the rejection.

“All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). (MPEP 2143.03).

With respect to independent claim 1, the Office Action asserts that Nash et al. disclose a release mechanism “is capable of positioning and releasing the flexible plug intravascularly”. Applicants respectfully disagree. Initially, Applicants note that Nash et al. do not appear to disclose the asserted capability. Additionally, Nash et al. expressly teach away from releasing the flexible plug intravascularly at column 6, lines 26-28. Accordingly, Nash et al. do not appear to teach at least this claim limitation. Hannam et al. do not appear to remedy the shortcomings of Nash et al. in this respect.

Furthermore, and without conceding the correctness of the rejection, independent claim 1 has been amended to clarify the relationship among certain claim elements. Nash et al. and Hannam et al., alone or in combination, do not appear to disclose or suggest a resilient extension member having a transverse aperture therein, and a suture passing through the aperture, wherein the suture is not directly connected to the flexible plug.

Turning to independent claim 40, the Office Action acknowledges that Nash et al. do not teach the plug “being sufficiently flexible to conform to and seal the blood vessel puncture”, and advances Hannam et al. as teaching this limitation. However, Applicants must respectfully point out that Nash et al. expressly teach an anchor is “sufficiently rigid” such that “it is resistant to deformation” (column 5, lines 56-60). Therefore, the proposed modification in view of Hannam et al. appears to be improper. MPEP 2143.01 sections V-VI state: “If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)”...“If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)”.

Additionally, the Office Action asserts that Nash et al. discloses a connector 78 is disposed between the disk and the hemostatic body. While Nash et al. do appear to disclose a spacer member 78 disposed between the flexible disk and the hemostatic body, spacer member 78 does not appear to couple the two elements. Instead, spacer member 78 appears to be just that – a slidable spacer that can be disposed between and spaced apart from the flexible disk and the hemostatic body. As clearly visible in Figures 4-9

and 19, spacer member 78 does not appear to couple the flexible disk to the hemostatic body.

For at least the reasons discussed above, Nash et al. in view of Hannam et al. do not appear to properly disclose or suggest all of the claim limitations of independent claims 1 and 40, as is required to establish a *prima facie* case of obviousness. Accordingly, claims 41-46 and 61, which depend from claims 1 and 40 and add additional elements thereto, are also believed to be patentable over the cited references. Applicants respectfully request that the rejection be withdrawn.

Claims 1, 40, 44-49, and 62 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kensey et al. (U.S. Patent No. 5,441,517) in view of Hannam et al. (U.S. Patent No. 5,649,959). After careful review, Applicants must respectfully traverse the rejection.

With respect to independent claim 1, the Office Action asserts that Kensey et al. disclose a release mechanism “comprising a hemostatic material 30 and a resilient extension member 704”. Applicants respectfully disagree. Initially, Applicants note that element 704 of Kensey et al. appears to be disclosed as the second tubular component of tamping means 700 (see column 14, lines 15-20), and does not appear to be attached to a top of the hemostatic material, as claimed. Additionally, and without conceding the correctness of the rejection, claim 1 has been amended to clarify the relationship among certain claim elements. Kensey et al. and Hannam et al., alone or in combination, do not appear to disclose or suggest a resilient extension member having a transverse aperture therein, and a suture passing through the aperture, wherein the suture is not directly connected to the flexible plug.

Kensey et al. and Hannam et al., alone or in combination, also do not appear to disclose or suggest “the release mechanism positioning and releasing the flexible plug intravascularly at the blood vessel puncture site”, as claimed. At least filament 34 appears to remain directly attached to the flexible plug, and Kensey et al. appear to teach away from the claimed release by expressly disclosing filament 34 as being “taped to the skin” (see column 13, line 68 to column 14, line 1; and column 14, lines 53-55). Filament 34, asserted to be part of the claimed release mechanism, does not appear to

detach from anchor member 32, and thus does not appear to release the flexible plug intravascularly, as claimed. Kensey et al. appear to rely upon filament 34 to apply tension to anchor member 32 thereby preventing intravascular release of the anchor member (see column 13, lines 36-41). Accordingly, Kensey et al. do not appear to teach all of the claim limitations of independent claim 1. Hannam et al. do not appear to remedy the shortcomings of Kensey et al. in this respect.

Turning to independent claim 40, the Office Action acknowledges that Kensey et al. do not teach the plug “being sufficiently flexible to conform to and seal the blood vessel puncture site”, and advances Hannam et al. as teaching this limitation. However, Applicants must respectfully point out that Kensey et al. expressly teach anchor member 32 is “stiff”, and “sufficiently rigid” such that “it is resistant to deformation” (column 5, lines 32-35; and column 7, lines 10-15). Therefore, the proposed modification in view of Hannam et al. appears to be improper. MPEP 2143.01 sections V-VI state: “If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)”...“If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)”.

Additionally, the Office Action asserts that Kensey et al. discloses a connector 504 between the disk and the hemostatic body. Applicants respectfully disagree. Element 504 appears to be disclosed as a passageway in sheath 28’ (see column 11, lines 57-58), and does not appear to overlap any element of the claim. Therefore, it is unclear how element 504 can be asserted to represent the claimed connector disposed between the flexible disk and the hemostatic body, coupling the disk to the body. Accordingly, Applicants submit that Kensey et al. do not appear to disclose or suggest all of the elements of independent claim 40. Hannam et al. do not appear to remedy the shortcomings of Kensey et al.

For at least the reasons discussed above, Kensey et al. in view of Hannam et al. do not appear to properly disclose or suggest all of the claim limitations of independent

claims 1 and 40, as is required to establish a *prima facie* case of obviousness. Accordingly, claims 44-49 and 62, which depend from claims 1 and 40 and add additional elements thereto, are also believed to be patentable over the cited references. Applicants respectfully request that the rejection be withdrawn.

Claim 27 was rejected under 35 U.S.C. §103(a) as unpatentable over Nash et al. (U.S. Patent No. 5,700,277) in view of Hannam et al. (U.S. Patent No. 5,649,959), as applied to claim 1, and further in view of Haaga (U.S. Patent No. 5,254,105). Applicants respectfully traverse the rejection.

As discussed above, independent claim 1 is believed to be patentable over Nash et al. and Hannam et al. Haaga does not appear to remedy the shortcomings of Nash et al. and Hannam et al. with respect to claim 1. Since claim 27 depends therefrom and adds additional elements thereto, Applicants submit that claim 27 is also patentable over the cited references and respectfully request that the rejection be withdrawn.

Conclusion

In view of the foregoing, all pending claims are believed to be in condition for allowance. Further examination, reconsideration, and withdrawal of the rejections are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By their Attorney,

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